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Appendix 14a

510(k) SUMMARY

Hill-Rom Manufacturing, Inc.
The WatchChild™ System

NAME	Hill-Rom Manufacturing
ADDRESS	1225 Crescent Green Suite 200 Cary, NC 27511
TELEPHONE:	919/854-3600
FAX	919/854-3217
CONTACT	Ms. Cindy L. Crosby
DATE SUMMARY PREPARED:	September 3, 2003

DEVICE NAME

Proprietary Name:	The WatchChild™ Obstetrical Patient Data Management System
Trade Name:	The WatchChild™ System
Classification Name:	Perinatal Monitoring System and Accessories

PREDICATE DEVICE

The device to which Hill-Rom is claiming substantial equivalence is The WatchChild™ System Obstetrical Patient Data Management System cleared for marketing by FDA in 510(k) K014094 on January 11, 2002.

DESCRIPTION OF DEVICE

The WatchChild™ Obstetrical Patient Data Management System (The WatchChild™ System) is a complete Obstetrical Information Management System that has the capability to record, store, and display fetal and maternal data from initial fetal stress tests through labor, delivery and discharge. Specifically, data from fetal monitoring and maternal vital signs monitoring equipment can be recorded, stored, and displayed on The WatchChild™ System via automation of the following areas:

- Admission/Discharge/Transfer (ADT)
- Labor and Delivery notes
- Nursing notes

- Physician's notes
- Fetal Strip faxing
- Obstetrical statistical trend reports, e.g., patient enrollments and discharges over time

The WatchChild™ System has the ability to simultaneously display graphic and text data on the same screen permitting the clinician to view a patient's fetal strip along with her medical data. Interaction with The WatchChild™ System is accomplished through a graphical user interface (GUI). The user activates buttons on the screen utilizing either a light pen or a mouse. The WatchChild™ System is offered with an optional optical disk archiving system (WORM technology) that replaces conventional paper storage. In addition, an optional physician's remote access is also available. Using a personal computer, a physician can call from outside the hospital and display real time and/or trended data for any patient connected to the system, as well as perform annotations to the patient's fetal strip.

The WatchChild™ System can be installed as a stand-alone system or connected to the Hospital's Information System.

INTENDED USE

The intended use of The WatchChild™ Obstetrical Patient Data Management System is a complete Obstetrical Information System which has the ability to record, store, and display data from fetal monitors and maternal vital signs monitors, and manages patient information from the initial Fetal Stress Tests through post delivery discharge. The WatchChild™ System organizes clinical data, which would normally be provided on paper records or other clinical systems and devices. This system serves as a decision support tool as well as an electronic medical record. This device is intended for use in a hospital/clinical environment.

Consistent with 21 CFR §801.109 The WatchChild™ System is considered a prescription use device.

COMPARISON OF DEVICE TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE

The WatchChild™ System that is subject of this submission is equivalent to the predicate device indicated above. The system has the same capabilities to record, display, and archive data collected from fetal and maternal monitors, nurse's and doctor's notes and annotations.

NONCLINICAL TESTING

Testing was conducted to verify and validate the software.

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CLINICAL TESTING

Clinical testing is not applicable for this device.

CONCLUSIONS

It is our conclusion that the data presented in this submission demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 8 2003

Ms. Cindy L. Crosby
Executive Director, Quality Assurance
and Regulatory Affairs
Hill-Rom Company, Inc.
1225 Crescent Green, Suite 200
CARY NC 27511

Re: K032772
Trade/Device Name: The WatchChild™ Obstetrical Patient Data Management System Version 7.2.0
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: September 5, 2003
Received: September 8, 2003

Dear Ms. Crosby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 7a

510(k) Number (if known) K032772

Device Name: The WatchChild™ Obstetrical Patient Data Management System

Indications For Use:

The intended use of the WatchChild™ Obstetrical Patient Data Management System is a complete obstetrical information system which has the ability to record, store, and display data from fetal monitors and maternal vital signs monitors, and manages patient information from the initial fetal stress tests through post delivery discharge. The WatchChild™ System organizes clinical data, which would normally be provided on paper records or other clinical systems and devices. This system serves as a decision support tool as well as an electronic medical record. This device is intended for use in a hospital/clinical environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032772